Notice of Allowability	Application No.	Applicant(s)	
	09/965,807	MATALON ET AL.	
	Examiner	Art Unit	
	Suzanne M. Mayer, Ph.D.	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *a telephone call from Mr. Richard Lebovitz, March 31, 2005*.

2. ☒ The allowed claim(s) is/are *22,24,67-75,89-90 and 92-94*.

3. ☒ The drawings filed on *04 February 2002* are accepted by the Examiner.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Richard Lebovitz on March 31, 2005.

The application has been amended as follows:

In the first line of the **specification**, please insert the following:

This application is a continuation of U.S. Ser. No. 08/128,120, filed Sept. 29, 1993, which is now abandoned.

Please amend the **claims** as follows:

Rewrite Claim 22 as follows: An isolated human aspartoacylase polypeptide having either an altered ability to hydrolyze N-acetyl-aspartic acid to aspartate and acetate, as compared with a wild-type human aspartoacylase, or incapable of hydrolyzing N-acetyl-aspartic acid to aspartate and acetate, and comprising the amino acid sequence SEQ ID NO: 2 of wild-type human aspartoacylase, except that said sequence has one or more of the following amino acid substitutions:

E285 > A,

Y231 > X, and/or

A305 > E.

Rewrite Claim 24 as follows: A human aspartoacylase of claim 22, wherein the glutamic acid at amino acid position 285 is substituted by alanine.

Cancel Claim 63.

Cancel Claim 66.

Rewrite Claim 67 as follows: A recombinant human aspartoacylase capable of hydrolyzing N-acetyl aspartic acid to aspartate and acetate, comprising an amino acid sequence which has a sequence identity of at least 95% to the sequence of SEQ ID NO: 2.

Rewrite Claim 68 as follows: A fragment of a recombinant ~~wild-type~~ human aspartoacylase of claim 67, comprising an aspartoacylase epitope which is immunologically-effective to elicit antibodies that selectively bind to said human aspartoacylase and which is capable of hydrolyzing N-acetyl aspartic acid to aspartate and acetate.

Rewrite Claim 69 as follows: A pharmaceutical composition, comprising an isolated wild-type human aspartoacylase comprising the amino acid sequence SEQ ID NO: 2, and a pharmaceutically acceptable carrier.

Rewrite Claim 70 as follows: An isolated wild-type human aspartoacylase comprising the amino acid sequence SEQ ID NO: 2, which is free of other cellular components.

Rewrite Claim 71 as follows: An isolated wild-type human aspartoacylase comprising the amino acid sequence SEQ ID NO: 2, which is free of other human proteins.

Rewrite Claim 72 as follows: A preparation which consists essentially of a wild-type human aspartoacylase comprising the amino acid sequence SEQ ID NO: 2.

Rewrite Claim 73 as follows: An isolated wild-type human aspartoacylase comprising the amino acid sequence SEQ ID NO: 2, in a concentration which can be administered to a patient at a dosage of 0.1 to 100 U/kg.

Rewrite Claim 74 as follows: A human aspartoacylase comprising the amino acid sequence SEQ ID NO: 2, or comprising an amino acid sequence which has a sequence identity of at least 95% to the sequence of SEQ ID NO: 2 produced by,

(a) culturing a host cell transformed with a vector comprising a DNA which encodes for said human aspartoacylase in a cell culture medium under conditions whereby the aspartoacylase is expressed, and

(b) isolating the thus-produced aspartoacylase.

Rewrite Claim 75 as follows: A human aspartoacylase comprising the amino acid sequence SEQ ID NO: 2, or comprising an amino acid sequence which has a sequence identity of at least 95% to the sequence of SEQ ID NO: 2, produced in a bacterium, a fungus, or a non-human mammalian cell.

Cancel Claims 80-88.

Rewrite Claim 89 as follows: An isolated human aspartoacylase capable of hydrolyzing N-acetyl aspartic acid to aspartate and acetate, comprising the amino acid sequence SEQ ID NO: 2, or comprising an amino acid sequence which has a sequence identity of at least 95% to the sequence of SEQ ID NO: 2, which is produced by expressing a DNA coding for said aspartoacylase in a host cell.

Rewrite Claim 90 as follows: An isolated human aspartoacylase of claim 89, comprising the amino acid sequence SEQ ID NO: 2.

Cancel Claim 91.

Add Claim 92 as follows: A recombinant human aspartoacylase having either an altered ability to hydrolyze N-acetyl-aspartic acid to aspartate and acetate, as compared with a wild-type human aspartoacylase, or incapable of hydrolyzing N-acetyl-aspartic acid to aspartate and acetate, and comprising an amino acid sequence which has a sequence identity of at least 95% to the sequence of SEQ ID NO: 2.

Add Claim 93 as follows: A fragment of a human aspartoacylase comprising SEQ ID NO: 2, which is immunologically-effective to elicit antibodies that selectively bind to said human aspartoacylase.

Add Claim 94 as follows: A fragment of claim 93, wherein said fragment comprises at least 26 amino acids.

2. The following is an examiner's statement of reasons for allowance: a thorough search of the application showed the claims to be novel and free of all prior art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzanne M. Mayer, Ph.D. whose telephone number is 571-272-2924. The examiner can normally be reached on Monday to Friday, 8.30am to 5.00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SMM
01 April, 2004

ROBERT A. WAX
PRIMARY EXAMINER
Art Unit 1653